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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/673,121	09/26/2003	Shripad S. Bhagwat	10624-133-999	1280

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JONES DAY
222 EAST 41ST ST
NEW YORK, NY 10017

EXAMINER	
KIM, JENNIFER M	

ART UNIT	PAPER NUMBER
1617	

DATE MAILED: 12/14/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/673,121	BHAGWAT ET AL.	
	Examiner	Art Unit	
	Jennifer Kim	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 July 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-87* is/are pending in the application.

4a) Of the above claim(s) *1-21,25-30,70-74 and 85* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *22-24, 31-69, 75-84, 86, 87* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Applicants' election without traverse of Group II, claims 22-69, 75-84, 86 and 87, drawn to a method of treating various disorders, classified in class 514 with the species set forth in Example 243 at page 219 of the specification and a species of a single disorder of cancer is acknowledged. The species requirement of active compound is withdrawn and the Examiner has examined all the compounds. However, a species of a single disorder of elected cancer still applies.

Accordingly, claims 1-21, 25-30, 70-74 and 85 are withdrawn from consideration and claims 22-24, 31-69, 75-84, 86 and 87 have been examined only to the extent of applicants' election.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 22-24, 75-84, 86 and 87 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the treatment of specific cancer, does not reasonably provide enablement for the treatment of the term "cancer". The specification does not enable any person skilled in the art to which it pertains, or

with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

3. Enablement is considered in view of the Wands factors (MPEP 2164.01(a)). These include: nature of the invention, breadth of the claims, guidance of the specification, the existence of working examples, predictability of the prior art, state of the prior art and the amount of experimentation necessary. All of the **Wands factors** have been considered with regard to the instant claims, with the most relevant factors discussed below.

Nature of the Invention: All of the rejected claims are drawn to a method of treating cancer in a subject with an effective amount of elected species of compound. The nature of the invention is extremely complex in that it encompasses the actual treatment of any cell proliferation disorder (i.e. cancer) such that the subject treated with above compound does not contract any cancer.

Breath of the Claims: The complex nature of the claims is greatly exacerbated by breath of the claims. The claims encompass treatment of a complex cell proliferation disorder in humans which has potentially many different causes (i.e. many different mutations or combination of mutations). Each of which may or may not be addressed by the administration of the claimed compound.

Guidance of the Specification: The guidance given by the specification as to how one would administer the claimed compounds to a subject in order to

actually treat **any cancer** is minimal. All of the guidance provided by the specification is directed towards treatment of specific cancer rather than treatment of **a cancer**.

Working Examples: All of the working examples provided by the specification are directed toward the treatment of specific cancer (e.g. lung cancer) rather than treatment of any cancer. It is to be noted that no data has been presented to establish that applicants' compound would act in the manner claimed as they relate to the treatment of cancer in general.

State of the Art: While the state of the art is relatively high with regard to treatment of specific cell proliferation disorders (e.g. lung cancer), the state of the art with regard to treatment of **any cancer** is underdeveloped. In particular, there do not appear to be any examples or teachings in the prior art wherein a compound similar to the claimed compounds was administered to a subject to treat development of **any or all cancer**. To the extent that the application is directed to a method of treating cancer cells in vivo, which is highly speculative, a greater amount of evidence is required to show its operability in humans. The difficulty in treating pancreatic, liver, colon and skin cancers is clearly known to the art as evidenced by the Carter et al. reference at pages 361 to 367. This illustrates that of approximately 35 drugs tested only 3 showed definite evidence of drug activity in the pancreas and only 4 in the colorectal and colon.

Predictability of the Art: The lack of significant guidance from the specification or prior art with regard to the actual treatment of any cancer in a human subject

with the claimed compound makes practicing the claimed invention unpredictable in terms of treatment of any cancer in general.

The amount of Experimentation Necessary: In order to practice claimed invention, one of skilled in the art would have to first envision a combination of appropriate pharmaceutical carrier, compound dosage, duration of treatment, route of administration, etc. and appropriate animal model system for one of the claimed compounds and test the combination in the model system to determine whether or not the combination is effective for the treatment of any cancer in general. If unsuccessful, which is likely given the lack of significant guidance from the specification or prior art regard to a treatment of any cancer with any compound, one of skill in the art would have to then either envision a modification of the first combination of pharmaceutical compound, compound dosage, duration of treatment, route of administration, etc. and appropriate animal model system, or envision an entirely new combination of the above, and test the system again. If again unsuccessful, which is likely given the lack of significant guidance form the specification of prior art regarding treatment of any cancer with any compound, the entire, unpredictable process would have to be repeated until successful. Therefore, it would require undue, unpredictable experimentation to practice the claimed invention to treat any or all cancer in general in a subject by administration of one of the claimed compounds.

Therefore, a method of treating a subject suffering any or all cancer administering elected compound is not considered to be enabled by the instant specification.

4. Claims 50-69, 75-84, 86 and 87 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the treatment of specific cancer, does not reasonably provide enablement for the "**preventing** cancer". The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

Claims 50-69, 75-84, 86 and 87 recited a method of treating or **preventing** cancer in a subject. The guidance given by the specification as to how one would actually practice the invention of **preventing** cancer is minimal. All of the guidance of the working examples are directed to the treatment. The specification teaches how to treat specific cancer (e.g. lung) in a subject however, there are **no working examples**, prophetic or otherwise in the specification how to **prevent cancer**. The state of the art with regard to determining the **prevention** of cancer in a subject is not predictable. Given the extremely complex nature of the invention, which involves preventing cancer, the breadth of the claims which encompass **prevention** of cancer, the complete lack of guidance from the specification regarding how to interpret the data generated by their methods toward understanding a **prevention** within a subject, **complete lack of working examples,** the uncertainty of whether the current state of the art regarding the use of such compound would **prevent** cancer. To the extent that the claims are

directed to a method of **preventing cancer** cells in vivo, which is impossible, a greater amount of evidence is required to show its operability in humans. The difficulty in **treating** pancreatic, liver, colon and skin cancers is clearly known to the art as evidenced by the Carter et al. reference at pages 361 to 367. This illustrates that of approximately 35 drugs tested only 3 showed definite evidence of drug activity in the pancreas and only 4 in the colorectal and colon. It would take undue, unpredictable experimentation to practice applicants invention to **prevent** cancer. Therefore, a method of **preventing** in a subject cancer administering compound set forth in claim 50 is not considered to be enabled by the instant specification. Therefore, a method of **preventing** cancer administering compound set forth in claim 50 is not considered to be enabled by the instant specification.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 22-24, 31-69, 75-84, 86 and 87 are rejected under 35 U.S.C. 102(e) as being anticipated by Reich et al. (U.S.2002/0161022).

Reich et al. disclose the compounds that are embraced by the instant claims which are useful in diseases/disorders such as cancer and proliferative disease. (see, abstract, and for example, compound 1 on page 19, second column; compound 3 on page 22, first column; etc.).

For these reasons the claimed subject matter is deemed to fail to patentably distinguish over the state of the art as represented by the cited references. The claims are therefore properly rejected under 35 U.S.C. 102(e).

None of the claims allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer Kim whose telephone number is 571-272-0628. The examiner can normally be reached on Monday through Friday 6:30 am to 3 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Sreenivasan Padmanabhan
Supervisory Examiner
Art Unit 1617

Jmk
October 18, 2004